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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,458	03/12/2001	Michael P. Maher	AUOBIO.026DV3	8760
20995	7590	11/19/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			OLSEN, KAJ K	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			1753	

DATE MAILED: 11/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/804,458

Applicant(s)

MAHER ET AL.

Examiner

Kaj K Olsen

Art Unit

1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,6-8,10-13 and 19-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,6-8,10-13 and 19-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10-15-04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.
2. Applicant should also fill in the missing information on p. 1. In the cases where these applications have matured into patents, applicant should also include that information.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, 6-8, 10, 13 and 19-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Baer et al (USP 5,128,257).
5. With respect to claim 1, Baer teaches an embodiment of an electrode assembly that has two electrodes (100, 102) that are parallel and non-overlapping and are disclosed as being placed into a well (i.e. a petri dish). See fig. 13 and col. 8, line 50 through col. 9, line 32. Although Baer does not explicitly state that the electrodes are adjacent to the bottom surface of the well, it is fairly clear that they are meant to be adjacent the bottom surface because the electrodes are mounted to a flat surface (col. 8, lines 58-60) and the only flat surface of a petri dish is the bottom surface of it (see fig. 2 as an example). Alternatively, in the event that Baer would not be

construed as teaching the use of the bottom surface, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to place this electrode configuration adjacent to the bottom surface because the bottom surface would allow the flat electrode assembly to come in best contact with the sample within the petri dish. With respect to the limitation concerning the mean field intensity over the specified area, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability. In addition, placing this electrode assembly adjacent the bottom of the well would clearly be capable of meeting the specified mean field intensity.

6. With respect to the claimed "assay plate", it doesn't appear that the applicant ever explicitly claims an assay plate and this plate thereby constitutes the intended use of the device (see alternative rejection with King below).

7. With respect to the new limitations requiring a plurality of cells having membrane ion channels (for the record, the examiner is considering the cells themselves to be now part of the claimed invention and are not intended use), Baer discloses the use of this device for the electroporation of cells (see abstract). Cells (both before and after electroporation) inherently require ion channels for the translocation of metabolites. With respect to the limitations drawn to how the potential differences are applied and how the cells respond to those potentials, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability.

8. With respect to the use of high optically transparent materials, see col. 4, lines 24-26.

9. With respect to "up to 96 wells", this would appear to read on anything from 1 to 96 wells and Baer teaches at least one well.

10. With respect to the electrode material, see col. 8, lines 64-66.
11. With respect to claims 19-22 (those limitations not already discussed above), Baer also discloses embodiments where at least three substantially planar electrodes are all placed substantially parallel to each other perpendicular to the bottom surface of the well. See fig. 4, 6, 7, and 9 and col. 7, lines 4-25.
12. With respect to the charging of one of the electrodes, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability.
13. With respect to second and third pairs of electrodes, Baer only appears to explicitly disclose five total electrodes. However, Baer teaches that additional electrodes are anticipated (col. 6, lines 56-60). The use of additional electrodes would mean that there would be at least 6 electrodes and that would read on the claimed second and third pairs.
14. Claims 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Arnold et al (USP 4,801,543).
15. These claims were previously rejected over Arnold (see details in the previous non-final and final office actions). With respect to the new limitations requiring a plurality of cells having membrane ion channels (for the record, the examiner is considering the cells themselves to be now part of the claimed invention and are not intended use), Arnold discloses the use of this device for cells (see examples 1-7). Cells inherently require ion channels for the translocation of metabolites. With respect to the limitations drawn to how the potential differences are applied and how the cells respond to those potentials, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 11 and 12 (and claims 1, 3, 6-8, 10, 13 in the alternative) are rejected under 35 U.S.C. 103(a) as being unpatentable over Baer in view of King et al (USP 6,352,853

19. With respect to claims 11 and 12, Baer disclosed all the limitations of the claims, but did not explicitly recite the use of greater than 96 or 384 wells. King discloses that an electroporation can be performed on a large scale by providing the samples to be electroporated in a plurality of wells, which allows simultaneous analysis of a number of samples while reducing the amount of materials needed for each analysis (col. 2, lines 50-65). The number of wells are typically multiples of 96, including 384 (col. 2, line 56). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of

King for the electrode assembly of Baer in order to reduce material waste and provide for simultaneous analysis of a plurality of samples.

20. With respect to the claims in the alternative, if the “assay plate” of these claims is construed as being part of the claimed invention and the petri dish of Baer is not construed as reading on an assay plate, then the sample well configuration of King would read on the assay plate. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of King for the electrode assembly of Baer because a plate having at least one well was known in the electroporation art as a means for holding sample and its use for the device of Baer would have required only routine skill in the art.

21. Claims 23-31, 34-39 and 41 are rejected over the teaching of Baer.

22. Claims 23-31, 34-39 and 41 are alternatively rejected under 35 U.S.C. 103(a) as being unpatentable over Baer in view of Matschke (USP 4,699,881) or Hilliard et al (USP 4,695,547). Both Matschke and Hilliard are being cited and relied on for the first time with this office action.

23. With respect to these claims (those limitations not discussed above), Baer does not explicitly recite a spacing from the bottom surface of the well to the bottom of the electrode. However, Baer appears to show that the electrodes lengths approximate the depth of the wells (see fig. 3 and 7 as an example), which would indicate the presence of a very small gap.

Furthermore, Baer discloses that the cells in the petri dish are grown at the bottom of the well (col. 6, lines 7-9), which would indicate that if one is desiring to treat bottom grown cells with an electric field, one would want to extend the electrodes as close as possible to the bottom of the well. Based on these two suggestions of Baer, one possessing ordinary skill in the art would have been motivated to utilize a very small spacing, including a spacing between 0.1 to 0.5 mm,

in order to ensure that the cells at the bottom of the well are suitably in the field lines for the electrodes.

24. Alternatively, Matschke discloses that a clearance 0.20 mm between an electrode and the bottom of the well was found to be a workable clearance in the art. See col. 5, lines 63-66.

Hilliard discloses a clearance between the electrode and the walls of the well of 0.5 mm (col. 3, lines 13-17). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teachings of either Matschke or Hilliard for the electrode assembly of Baer in order to ensure the cells at the bottom of the well are within the electric field lines and these secondary teachings demonstrate that a 0.1 to 0.5 mm spacing was both known in the art and was mechanically feasible.

25. With respect to the electrode spacing for this embodiment of Baer, see col. 6, line 56 through col. 7, line 3.

26. With respect to the presence of an insulator, see fig. 7 and col. 5, lines 39-41.

27. Claims 32 and 33 (and claims 23-31, 34-39 and 41 in the alternative) are rejected under 35 U.S.C. 103(a) as being unpatentable over Baer (with or without Matschke and Hilliard) in view of King.

28. With respect to claims 32 and 33, Baer disclosed all the limitations of the claims, but did not explicitly recite the use of greater than 96 or 384 wells. King discloses that an electroporation can be performed on a large scale by providing the samples to be electroporated in a plurality of wells, which allows simultaneous analysis of a number of samples while reducing the amount of materials needed for each analysis (col. 2, lines 50-65). The number of wells are typically multiples of 96, including 384 (col. 2, line 56). It would have been obvious to

one of ordinary skill in the art at the time the invention was being made to utilize the teaching of King for the electrode assembly of Baer in order to reduce material waste and provide for simultaneous analysis of a plurality of samples.

29. With respect to the claims in the alternative, if the “assay plate” of these claims is construed as being part of the claimed invention and the petri dish of Baer is not construed as reading on an assay plate, then the sample well configuration of King would read on the assay plate. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of King for the electrode assembly of Baer (with or without the teaching of Matschke or Hilliard) because an plate having at least one well was known in the electroporation art as a means for holding sample and its use for the device of Baer would have required only routine skill in the art.

30. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baer (with or without the teachings of Matschke, Hilliard or King) in view of Papp et al (USP 5,422,272).

31. Baer and King (with or without the teachings of Matschke, Hilliard or King) set forth all the limitations of the claim, but did not explicitly recite the presence of two insulators substantially perpendicular to the bottom surface of the well. Papp teaches the presence of two insulators (7, 8) that are parallel to two electrodes in order to provide the desired spacing between the electrodes and to make the electrode more mechanically stable. See fig. 2A and col. 3, lines 45-50. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Papp for the electrode assembly of Baer (with or without the teachings of Matschke, Hilliard or King) in order to make the electrodes more mechanically stable.

Response to Arguments

32. Applicant's arguments filed 9-8-2004 have been fully considered but they are not persuasive. Applicant urges that the new claim language reads free of the prior art. However, the only structural limitation added to the claims of the instant invention is the presence of a cell having membrane ion channels. Because all the prior art (most importantly the primary teachings Baer and Arnold) are drawn to devices to be useable with cells (and cells inherently require membrane ion-channels for the translocation of metabolites), the presence of cells is anticipated.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 5:30 A.M. to 3:00 P.M. and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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November 18, 2004



KAJ K. OLSEN
PRIMARY EXAMINER